510(k) Summary

NOV 17 2009

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	2009-July-24
510(k): Number:	K092271
Submitter:	GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC. 9900 Innovation Drive Wauwatosa, WI, USA 53226
Primary Contact Person:	Nicole Landreville, Eng. RAC USA Premarket Regulatory Affairs Leader GE Healthcare 3000 North Grandview Boulevard #W450 Waukesha, WI, USA 53188 Telephone: 289-208-2365 Fax: 414-918-4498
Secondary Contact Person:	James T. Turner, MS, RAC USA Premarket Regulatory Affairs Leader GE Healthcare 3000 North Grandview Boulevard #W450 Waukesha, WI, USA 53188 Telephone: 262-544-3359 Fax: 414-908-9225
Device/Trade Name:	GE LOGIQ E9 BT2010 Diagnostic Ultrasound System
Common/Usual Name:	LOGIQ E9
Classification Names and Product Code:	Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Classification:	Class II
Predicate Device(s):	K082185 GE LOGIQ E9 Diagnostic Ultrasound System K081921 GE Vivid E9 Diagnostic Ultrasound System K083095 SonixTouch Ultrasound Scanner
Device Description:	The LOGIQ E9 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 58 cm wide, 86 cm deep and 141 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10-inch LCD touch screen and color 19-inch LCD image display. This modification will provide users with 8 additional transducers, an additional optional feature called Elastography Imaging and an enhanced version of the commercially available Volume Navigation (V Nav) optional feature. These modifications all lead to overall quality and image enhancement.

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Intended Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

Technology: The LOGIQ E9 BT2010 employs the same fundamental scientific technology as its predicate devices. In addition to the 13 transducers commercially released: 3CRF, 9L-D, 11L-D, C1-5-D, IC5-9-D, M4S-D, M6C-D, ML6-15-D, RAB2-5-D, RIC5-9-D, RNA5-9-D, RSP6-16-D, S1-5, the LOGIQ E9 Diagnostic Ultrasound System will be released with these additional 8 transducers: 6S-D, 6Tc, L8-18i-D, M5S-D, P2D, P6D, RAB4-8-D and S4-10.

Additional Features Description:

1. Elastography imaging mode on the LOGIQ E9 is similar to the Elastography imaging mode on the Ultrasonix SonixTouch Ultrasound Scanner. Elastography is a method to extract and display the mechanical properties of tissue.
This imaging method involves applying a manual pressure with the hand on the transducer. The actual imaging sequence is similar to the B-mode sequence except that the system will acquire the RF signal instead of acquiring B-mode data. The acoustic output transmission is identical to B-mode data. The algorithm extracts a strain value information for every point on the image. The Elastography image then color-codes the stiff versus softer structures. The clinical benefits of elastography imaging are still under evaluation. This feature allows the user to be able to determine whether or not a structure inside the patient is stiffer than another one; no clinical diagnostic claims are being made.
This submission includes a document "DOC0605013 Verification Results Summary for Elastography Imaging". The report provides evidence that the elasticity imaging algorithm can differentiate different structures with different stiffness.

2. Volume Navigation (V Nav) feature was modified from its previous version cleared under 510(k) K082185. The Volume Navigation feature is enhanced with needle tracking. Volume Navigation uses one or more Electromagnetic (EM) position sensors attached to the transducer to track its movement. Needle Tracking is achieved by using an additional EM sensor attached to the needle.
This submission includes a document "DOC0631792 Verification Results Summary for Volume Navigation". The report provides evidence that the V Nav feature functions according to requirements and specifications.

Determination of Substantial Equivalence: <u>Summary of Non-Clinical Tests:</u>
The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The LOGIQ E9 BT2010 and its applications comply with voluntary standards as detailed in Section 9, 11, 15 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Management
- Requirements Reviews

- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer material and other patient contact materials such as needle guidance kits are biocompatible.

Summary of Clinical Tests:
The subject of this premarket submission, LOGIQ E9 BT2010, did not require clinical studies to support substantial equivalence.

Conclusion: The GE LOGIQ E9 BT2010 is of a comparable type and substantially equivalent to the current GE LOGIQ E9, GE Vivid E9 and the Elastography Imaging feature from SonixTouch Ultrasound Scanner. It has the same technological characteristics, key safety and effectiveness features, and is similar in physical design, construction and materials and has the same intended uses and basic operating modes as the predicate devices.

Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms to 21 CFR 820, ISO 9001 and ISO 13485 quality management systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the LOGIQ E9 BT2010 is as safe, as effective, and performance is substantially equivalent to the predicate devices(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Nicole Landreville
USA Premarket RA Leader
GE Healthcare
3000 N. Grandview Blvd., W450
WAUKESHA WI 53188

NOV 17 2009

Re: K092271
Trade/Device Name: GE LOGIQ E9 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: October 15, 2009
Received: October 26, 2009

Dear Ms. Landreville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ E9 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3CRF	11L-D	M4S-D
6S-D	C1-5-D	M5S-D
6Tc	IC5-9-D	M6C-D
9L-D	L8-18i-D	ML6-15-D

P2D	RAB4-8-D	RSP6-16-D
P6D	RIC5-9-D	S1-5
RAB2-5-D	RNA5-9-D	S4-10

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K092271

Device Name: GE LOGIQ E9 Diagnostic Ultrasound System

Indications For Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription Use (Per 21 CFR 801.109)

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the **LOGIQ E9** system and for all of its probe/mode combinations. Combinations identified by "N" are new while "P" represents those previously cleared with the unmodified LOGIQ E9. In a similar manner, "E" represents combinations added to the unmodified LOGIQ E9 via Appendix E of the 510(k) Guidance. The subject modification does not alter the previously cleared system level indications, clinical applications or modes of operation.

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Small Organ[2]	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Musculo-skeletal Superficial	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Other[4]	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Transvaginal	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Transurethral											
Intraoperative[8]	P	P	P	P	P	P	P	P	P	P	[3, 5, 6, 9]
Intraoperative Neurological	P	P	P	P	P	P	P	P	P	P	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with 3CRF Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N		N	N	N	N	N	N	[5, 6, 9]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[5, 6, 9]
Pediatric	P	P	P		P	P	P	P	P	P	[5, 6, 9]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P		P	P	P	P	P	P	[5, 6, 9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with 6S-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N	N	N	N	N	N	N	N	
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ[2]											
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with 6Tc Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult	N	N	N	N	N	N	N	N	N	N	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal	N	N	N	N	N	N	N	N	N	N	
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with 9L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N		N	N	N	N	N	N	[5, 6, 9]
Abdominal[1]	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Pediatric	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD. System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with 11L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]	N	N	N		N	N	N	N	N	N	[3, 5, 6]
Pediatric	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
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[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with C1-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD. System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with IC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5, 6, 9]
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Transvaginal	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with L8-18i-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Small Organ[2]	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Neonatal Cephalic	N	N	N		N	N	N	N	N	N	[5, 6, 9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]	N	N	N		N	N	N	N	N	N	[3, 5, 6, 9]
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with M4S-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5, 6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD. System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with M5S-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Pediatric	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	[9]
Cardiac Adult	N	N	N	N	N	N	N	N	N	N	
Cardiac Pediatric	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode..
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with M6C-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[5, 6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5, 6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with ML6-15-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Neonatal Cephalic	N	N	N		N	N	N	N	N	N	[9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[3, 5, 6, 9]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD. System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic			N	N							
Cardiac Adult			N	N							
Cardiac Pediatric			N	N							
Peripheral Vascular			N	N							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with P6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic			N	N							
Cardiac Adult			N	N							
Cardiac Pediatric			N	N							
Peripheral Vascular			N	N							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD; B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with RAB2-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5, 6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[5, 6]
Pediatric	P	P	P		P	P	P	P	P	P	[5, 6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5, 6]
Musculo-skeletal Superficial											
Other[4]	P	P	P		P	P	P	P	P	P	[5]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with RAB4-8-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N		N	N	N	N	N	N	[5, 6]
Abdominal[1]	N	N	N		N	N	N	N	N	N	[5, 6]
Pediatric	N	N	N		N	N	N	N	N	N	[5, 6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	[5, 6]
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with RIC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5, 6]
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	N	N	N		N	N	N	N	N	N	[3, 5, 6]
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Transvaginal	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with RNA5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6]
Small Organ[2]	P	P	P	P	P	P	P	P	P	P	[5,6]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with RSP6-16-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[3, 5, 6]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological	P	P	P		P	P	P	P	P	P	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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510(k) Number K092271

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with S1-5 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[5, 6, 9]
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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510(k) Number K092271

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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ E9 with S4-10 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Pediatric	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Small Organ[2]	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	[5, 6, 9]
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.
[2] Small organ includes breast, testes, thyroid.
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate.
[5] 3D/4D Imaging Mode.
[6] Needle guidance imaging.
[7] Includes infertility monitoring of follicle development.
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[9] Volume Navigation.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes.

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